

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALLERGAN, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 17-663-JFB-SRF
)	
TARO PHARMACEUTICAL)	UNDER SEAL
INDUSTRIES LTD. and TARO)	
PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

In this patent infringement action filed under the Hatch-Waxman Act by plaintiff Allergan, Inc. (“Allergan”), against defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc. (together, “Taro”), Allergan alleges infringement of U.S. Patent No. 9,517,219 (“the ‘219 patent”) under the doctrine of equivalents. (D.I. 1 at 1) Presently before the court is the matter of claim construction. Below is the court’s recommendation for the construction of the disputed claim term.

II. BACKGROUND

Allergan is the assignee of the ‘219 patent, entitled “Topical Dapsone and Dapsone/Adapalene Compositions and Methods for Use Thereof,” which issued on December 13, 2016. (D.I. 1 at ¶ 18) The ‘219 patent covers the product Aczone® Gel 7.5% (“Aczone”), a once-daily product used to treat acne vulgaris. (*Id.* at ¶¶ 17, 19) On February 24, 2016, the Food and Drug Administration (“FDA”) approved the marketing of Aczone in accordance with Allergan’s New Drug Application (“NDA”) No. 207154. (*Id.* at ¶ 19)

The active pharmaceutical ingredient (“API”) in Aczone is dapsone. (*Id.* at ¶ 17) The ‘219 patent describes a method for treating a variety of dermatological conditions by administering a topical pharmaceutical composition that includes about 7.5% dapsone, water, 30% to 40% of diethylene glycol monoethyl ether (“DGME”), and a 2% to 6% polymeric viscosity builder (“PVB”) that includes a polymer called acrylamide/sodium acryloydimethyl taurate copolymer (“A/SA”). (‘219 patent col. 16:2-40) Allergan identifies this new PVB containing A/SA as Sepineo™ P 600 (“Sepineo”). (D.I. 57, Ex. B at 6-8) The use of a PVB has been found to decrease “the intensity of yellowing of the composition caused by the increased solubility of dapsone in DGME.” (‘219 patent, col. 2:54-57) Additionally, the PVB helps improve dapsone crystallization which results in compositions with better aesthetics. (*Id.* at col. 2:57-60)

Taro manufactures and sells generic copies of branded pharmaceutical products. (D.I. 1 at ¶ 5) Taro submitted an Abbreviated New Drug Application (“ANDA”) No. 210191 to the FDA for approval of a generic version of Aczone prior to the expiration of the ‘219 patent. (*Id.* at ¶ 20) Taro’s proposed generic version of Aczone uses Carbopol® 980 (“Carbopol”) as the PVB. (D.I. 56 at 1, 4)

There is no dispute between the parties that Taro’s product does not contain A/SA. Therefore, Allergan does not contend that Taro literally infringes the ‘219 patent. However, Allergan alleges that Taro’s product infringes the ‘219 patent through the doctrine of equivalents because it includes a PVB equivalent to Sepineo, the PVB used in Aczone. (D.I. 1 at ¶ 33)

Presently before the court is the parties’ dispute regarding the construction of the term “polymeric viscosity builder.”

III. LEGAL STANDARD

Construing the claims of a patent presents a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996)). “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the court may attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

The words of the claims “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted); *see also Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016). Claim terms are typically used consistently throughout the patent, and “usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Phillips*, 415 F.3d at 1314 (observing that “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . .”).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a

presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003) (citing *Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1375 (Fed. Cir. 2002)).

Other intrinsic evidence, including the patent specification, “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff’d*, 481 F.3d 1371 (Fed. Cir. 2007). The specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is also “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent

and Trademark Office] and includes the prior art cited during the examination of the patent.”

Phillips, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

A court also may rely on “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.*

(“[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.”). Overall, while extrinsic evidence may be useful to the court, it is less reliable than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.”

Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

IV. CONSTRUCTION OF “POLYMERIC VICSOCSTY BUILDER” (‘219 patent, claims 1, 3, 6)

Allergan	Taro	Court
“polymer-based system with one or more components that contributes to creating or maintaining the viscosity of the topical pharmaceutical composition”	“a polymer or polymer-based thickening agent”	“a polymer or polymer-based thickening agent”

I recommend that the court adopt Taro’s proposed construction, in accordance with the intrinsic evidence. At oral argument, the parties satisfied the court’s inquiry that there is agreement that “one or more” components is already incorporated into the term “comprising,” which appears in independent claim 1 and, by reference, in dependent claims 3 and 6 of the ‘219 patent.¹ Furthermore, Allergan does not dispute that its reference to “system” in its proposed construction may be construed as equivalent to “agent,” as referenced in Taro’s proposed construction.²

¹ Claim 1 of the ‘219 patent claims a PVB “comprising [A/SA] copolymer.” (‘219 patent, col. 16:8-10) Allergan suggests that the “one or more” language in its proposed construction is necessary to clarify that the PVB “need not be a single agent, but may instead be made of *one or more* components.” (D.I. 58 at 3) However, Taro responds that “[t]he term ‘comprising’ necessarily allows for one or more components, a point to which Taro has never disagreed, as noted by the inclusion of ‘polymer-based’ in Taro’s construction of PVB.” (D.I. 64 at 6) For purposes of this claim construction, the court recommends that “comprising” means a PVB having one or more components. *See CLAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) (“In the patent claim context the term ‘comprising’ is well understood to mean ‘including but not limited to.’”).

² Allergan provides no intrinsic support for its characterization of a PVB as a polymer-based “system.” As noted by Taro, this addition could effectively broaden the claim language without adequate intrinsic support. Moreover, during oral argument, counsel for Allergan represented that “system” is not substantively different from “agent.”

Allergan alleges that Taro's proposed construction reads "builder" out of the claims. (D.I. 58 at 8) Taro counters that its proposed construction accounts for the word "builder" because a "thickening agent" increases viscosity by definition. (D.I. 64 at 6-7) The other significant dispute centers on whether "viscosity" is equivalent to "thickening." Allergan argues against such a construction, contending that "[v]iscosity is a composition's resistance to flow." (D.I. 58 at 3 n.2) (internal quotation marks and citations omitted).

The specification supports Taro's construction of the term PVB because it uses the term interchangeably with thickener or polymeric thickener. The language of claim 1 describes "a polymeric viscosity builder comprising [A/SA] copolymer," thereby establishing that the patentee understood the A/SA copolymer to be a PVB. ('219 patent, col. 16:8-10) In accordance with the claim language, the specification refers to the A/SA copolymer as a copolymer based thickener in Example 1, which identifies "two formulations . . . that show the impact of [A/SA] copolymer based thickener on dapsone particle size," and refers to the "impact of [A/SA] copolymer based thickener on dapsone crystal growth" in Figure 2. ('219 patent, col. 12:45-53) Table 1 also identifies the A/SA copolymer based thickener as the PVB in the context of dapsone formulations. (*Id.* at col. 12:60-13:10) The description of the A/SA copolymer as a "polymeric viscosity builder" in claim 1 of the '219 patent, viewed in light of the specification's repeated references an A/SA copolymer based thickener, establishes that the term "polymeric viscosity builder" is equivalent to a polymer or polymer-based thickening agent in the context of the '219 patent.

The prosecution history further supports Taro's position that the PVB is equivalent to a polymeric thickening agent, thickening agent, or a thickener. In the patentee's February 18, 2016 response to the examiner's office action, the patentee distinguished the invention of the

'219 patent over the prior art by explaining that the '219 patent employs an A/SA copolymer as "an entirely new thickening agent" without a carbomer such as Carbopol 980, which was the thickening agent used in the prior art. (D.I. 57, Ex. B at 6) The patentee acknowledged that, while another prior art reference used an A/SA copolymer as an additional thickener, it did not teach the use of the A/SA copolymer "as the sole thickener in a topical dermatological formulation prepared with an [API]." (*Id.*) The patentee emphasized that Sepineo "performed surprisingly better" than the PVBs used in the prior art, "and proved to be a more robust thickening agent" capable of thickening formulations while providing a smaller dapsone particle size distribution. (*Id.* at 8)

The examiner also understood the claimed "polymeric viscosity builder" to refer to a "thickening agent or thickener as part of the carrier, such as, e.g., polymeric thickeners, to increase viscosity, stability and improve suspending capability when added to a mixture." (D.I. 57, Ex. L at 8) In withdrawing the obviousness rejection prior to allowance, the examiner was persuaded by the Warner Declaration, drafted by co-inventor Kevin S. Warner. (*Id.*, Ex. F at 2-4) The Warner Declaration describes the inventors' "evaluation of thickeners suitable for use in the dapsone 7.5% gel formulation," which revealed Sepineo P 600 to be "a more robust thickener and therefore more desirable for use in the gel formulation." (*Id.*, Ex. E at ¶¶ 6-7)

This evidence establishes that the inventors and the examiner understood the claimed PVB to be a thickener or thickening agent. Contrary to Allergan's contentions, Taro's proposed construction does not read the word "builder" out of the claimed "polymeric viscosity builder" because the intrinsic record demonstrates that a thickening agent functions to increase, or build, a formulation's viscosity.

Allergan's proposed construction does not substantively conflict with Taro's proposal, but it includes superfluous language which could lead to unnecessary confusion. For these reasons, I recommend that the court adopt Taro's proposed construction, which finds more support in the intrinsic record.

V. CONCLUSION

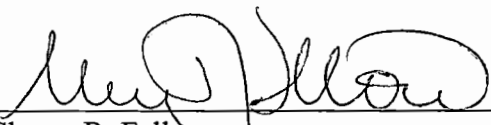
For the foregoing reasons, I recommend that the court adopt Taro's proposed construction and construe "polymeric viscosity builder" to mean "a polymer or polymer-based thickening agent."

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties should jointly submit a proposed redacted version by no later than **June 29, 2018**. The court will subsequently issue a publicly available version of its Report and Recommendation.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objection and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, <http://www.ded.uscourts.gov>.

Dated: June 6, 2018


Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE